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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/966,036	09/28/2001	Dorrie M. Happ	50623.132	4580

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EXAMINER

FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 11/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/966,036

Applicant(s)

HAPP, DORRIE M.

Examiner

Blessing M. Fubara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-5, 7-11, 14-17, 19, 21 and 23-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 28-30 and 33-35 is/are allowed.
- 6) ☒ Claim(s) 2-5, 7-11, 14-17, 19, 21, 23-27, 31, 32, and 36-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Examiner acknowledges receipt of request for extension of time, amendment and remarks filed 09/10/04. Claims 2-5, 7-11, 14-17, 19, 21 and 23-48 are pending.

NEW MATTER

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 2-5, 7, 15-17, 21, 23-25, 27, 32, 39, 42 and 44-48 are rejected under 35

U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is no support in the specification as originally filed for the expression "first layer" or "second layer" Applicants in the remarks on page 8, line 6, of the amendment filed 09/10/04 point out that the expression is fully supported by the specification. However, it is the examiner's position that there is no support for the expression. **In accordance with the MPEP, applicants should specifically point out support for any amendments to the claims in the disclosure.**

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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4. Claim 26 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 26 is vague because it is not clear what the recitation of “wherein at least of the layers of the coating material includes a polymer,” means. For examination purposes, the claim is interpreted as having at least one of the layers of the coating material to include a polymer.

Claim Rejections - 35 USC § 102

5. Claims 2-5, 7-11, 14, 19, 21, 25, 31, 36-38 and 40 remain rejected under 35 U.S.C. 102(e) as being anticipated by Harish et al. (US 2002/0122877 A1) .

Applicants argue that Harish does not disclose the coating structure of the instant claims 8, 19, 36-38 and 40 where the medical device includes a drug layer containing a drug and polymer, a drug-free top coat layer disposed over the drug layer and a film forming layer disposed over the top coat layer and where a light- and/or UV-protective compound is included in the film-forming layer. Applicants also argue that Harish does not disclose a coating configuration that includes three different layers each having a different function and that Harish does not suggest that the optional topcoat should have a radiopaque element and that UV-protective compound does not qualify as an active agent.

Regarding claims 2-5, 7, 9-11, 21 and 23-35, applicants argue that Harish does not disclose the precise mass ratios claimed by the present invention and with respect to claims 5, 15 and 45, that Harish does not disclose explicitly or implicitly the presence of a second layer where the mass ratio is between the light- and/or UV-protective compound and the polymer in the

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second layer is between about 3:1 and about 1:3. Furthermore, applicants argue that with respect to claims 9, 26, 28 and 33, Harish does not disclose a coating that has a layer containing a drug, a polymer and a light- and UV-protective compound where the ratio between the components is specifically between about 1:1:2 and about 1:3:20. Applicants further state that the sufficient amount of radioactive isotopes taught by Harish is only sufficient with respect to the amounts necessary for allowing a physician to view the stent and thus Harish does not provide direction on how much of the radiopaque elements might be needed to protect the underlying drug molecules from degradation caused by harmful radiation.

6. Applicants' arguments filed 09/10/04 have been fully considered but they are not persuasive.

Regarding the mass ratio's, the rejection of those claims having the mass ratios, that is claims 15-17, 21, 23, 24, 26-30, 32-35 and new claims 39, 41-43 and 45-48 are not included in the 102 rejection. Although, applicants argue that Harish fails to disclose the mass ratios, applicants provided no demonstration that the mass ratios and the thickness of any of the layers provides unusual results since mass ratios and thicknesses would be obvious variation.

The coating structure now recited is new matter. However, Harish is still relevant to the claims because Harish discloses coating layers that have active agents such as paclitaxel, docetaxel, actinomycin and vincristine. The coating composition also contains radiopaque elements such as gold.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 15-17, 21, 23-25, 26, 27, 32, 42 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harish et al. (US 2002/0122877 A1).

Harish is discussed in the previous rejection. Applicants agree that the difference between Harish and the instant claims is the mass ratio. Regarding the thickness of the layer, it is not inventive to determine or work out the thickness of the layer in the absence of a showing indicating how the thickness provides unusual results to the coated stent or medical device. Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the coating composition of Harish and use it to coat the medical device according to Harish. One having ordinary skill in the art would have been motivated to use a ratio in appropriate amounts of the coating compositions in the various layers and in the absence of a showing, the molar ratio between the coating layers is critical.

9. Claims 41, 43, 44 and 46-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harish et al. (US 2001/0122877 A1).

Harish is discussed in the previous rejection. Harish is silent on the thickness of the layer, it is not inventive to determine or work out the thickness of the layer in the absence of a showing indicating how the thickness provides unusual results to the coated stent or medical

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device. Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the coating composition of Harish and to coat the stent or medical device with the coating composition where the coat has the desired thickness with the expectation of effecting the desired release of the active agents from the coated medical device; and in the absence of a showing, the thickness of the coating of the medical device is not critical over the prior art. One having ordinary skill in the art would have been motivated to use a ratio in appropriate amounts of the coating compositions in the various layers and in the absence of a showing, thickness of the coating layers is critical.

Claims 28-30 and 33-35 are allowable over the prior art because the prior art does not disclose the limitations of claims 28 and 33.

10. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is requested in correcting any errors of which applicants may become aware in the specification.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,


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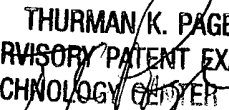
however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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